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December 6, 1999

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1916 - 1997

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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RE: DOCKET #97N-484S

To Whom It May Concern:

It has recently come to my attention that there is an attempt to regulate allograft tissue. As a neurosurgeon, I am dependent upon the use of allograft bone material in many surgical procedures, especially spinal fusions and spinal reconstructions. This tissue currently comes from bone banks and they have provided excellent service in supplying the medical community and hospitals with the necessary allograft bone. There is no logical reason for allograft bone to be classified as a medical device and have to undergo FDA testing and trials. It is not a mechanical or artificial substance. For most cases, we use the patient's own bone but in some cases we need to use donor bone or supplement the patient's own bone with donor bone. We are merely using the calcium and hydroxy apatite substructure of the bone in these cases. The only difference between using the donor bone and the patient's own bone is the fact that the bone has been processed and the marrow and other soft-tissue components have been removed and sterilized.

The potential allograft as medical devices will provide undue hardship and difficulties both in

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the maintenance of bone supplies but undoubtedly in the cost of such materials. I request that you drop any plan to alter the current system.

Respectfully,

F. David Barranco, M.D.

FDB/sa

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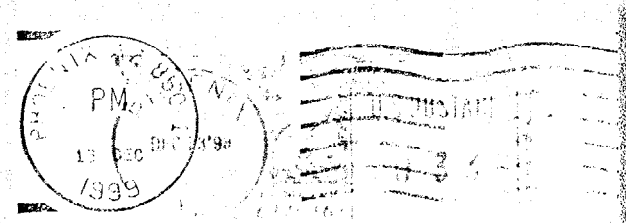

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